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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,556	05/03/2001	Andrew H. Cragg	AXIAMD.005CP1	6145

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EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

CS

Office Action Summary	Application No.	Applicant(s)	
	09/848,556	CRAGG, ANDREW H.	
	Examiner	Art Unit	
	Pedro Philogene	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *2,3,9,12,13,19 and 48-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,10,11,14-18 and 20-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08092004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Applicant's election without traverse of Group I claims 1,4-8,10,11,14-18,20-47 in the reply filed on 08/05/04 is acknowledged.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,4-8,10,11,14-18,20-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-86 of U.S. Patent No. 6,558,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims 1,11,20,26,34,40, 43, 45 are to be found in claims 1-86. The difference between the claims in the application and the claims in the patent lies in the fact that the patent claims includes many more elements and are thus much more specific. Thus the invention of the claims in the patent is in effect a "species" of the "generic" claims in the application. It has been held that the generic invention is "anticipated by the "species".

See in re Goodman, 29 USPQ 2d 2010 (Fed. Cir. 1993). Since the claims in the application are anticipated by the claims in the patent, the are not patentably distinct.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4,5,7,8,10,14,16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims depend on a non-elected claim and are therefore indefinite. For purpose of examination the above claims would be considered as depending on claims 1 and 11 respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,4-8,10,11,14-18,40-42,45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich et al. (6,086,589).

With respect to claims 1, 11, 40, 45 Kuslich et al discloses a method of treating the spine, comprising the steps of identifying a site on the anterior or posterior surface of the sacrum (12) forming a lumen (22) from the site through the sacrum, through the disc(18) and into at least one vetevrae; and performing a procedure using the lumen; as set forth in column 2, lines 27-67.

With respect to claims 4-8, 10, 14-18, 41-42,46-47, Kuslich et al disclose all the method steps, as set forth above.

Claims 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Helm et al., (6,805,697).

With respect to claims 43,44 Hem et al disclose a method comprising the steps advancing a device (40) through an access pathway to the procedure site the device having a first crossing profile; and enlarging the crossing the crossing profile of the device at the treatment site to perform the procedure; as best seen in FIGS.10-11, wherein the advancing steps comprises advancing the device through at least one vertebrae and at least one disc; as best seen in FGIS.10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-35,43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helm et al. (6,805,697).

With respect to claims 34-35, 43-44, it is noted that Helm et al disclose all the limitations; except for a passageway having a length 5 to10 times its width. However, it would have been obvious to one having ordinary skill in the art to multiply the width of the device of Helm et al, since such a modification would have involved a mere change in size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. (6,086,589).

With respect to claims 20-32, it is noted that Kuslich et al did not teach of a site within 5 cm from the coccyx; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to pla ce the site any distance from the coccyx, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helm et al. (6,805,697) in view of Kuslich et al. (6,086,589).

With respect to claims 36-39, it is noted that Helm et al., did not teach of an anterior or posterior passageway and a fixation device; as claimed by applicant. However, in a similar art, Kuslich et al., evidences the use of a anterior or posterior passageway and a fixation device to allow bone and fibrous through growth to stabilize the vertebrae.

Therefore, given the teaching of Kuslich et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Helm et al., as taught by Kuslich et al to provide a passageway and fixation device to allow bone and fibrous through growth to stabilize the vertebrae.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

4,175,555	11-1979	Herbert.
6,395,034	15-2002	Suddaby

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is(571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
November 09, 2004

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER